

**REMARKS**

**Formal Matters**

Claims 1 and 224-234 are pending after entry of the amendments set forth herein.

Claims 2-223 have been canceled, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Claims 231-234 have been newly presented.

Claims 1 and 224-230 were examined.

Claims 1 and 224-230 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

**The Telephone Interview**

Applicants wish to extend their appreciation to the Examiner for the courtesy provided to Applicants' representative during the telephone interview of July 11, 2011. During the Interview, it was agreed that Boyd et al., U.S. Patent No. 5,799,661 discloses a resilient member and, as such, the resilient member is not a malleable member shapeable to engage the surface of the beating heart, wherein said malleable member is continuously adjustably shapeable by manipulation thereof to a desired shape, and wherein upon release of manipulation forces, said malleable member maintains said desired shape and maintains said a contact surface in said desired shape, nor is the resilient member of Boyd et al. capable of functioning as a malleable member as claimed. Accordingly, it was agreed that the above claims patentably define over the Boyd et al. reference and that the rejection over Boyd et al. will be withdrawn. It was further agreed that claim 224 was substantially redundant of independent claim 1 and that Applicants would either cancel claim 224 or amend it so that it is no longer substantially redundant of claim 1.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in his next communication so that Applicants can amend or supplement the interview summary.

## **The Office Action**

### **Claim 224 Objected To Under 37 CFR 1.75(c)**

In the Official Action of June 17, 2011, claim 224 was objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner asserted that claim 224 recited that the contact member is continuously adjustable but that this feature is already recited in independent claim 1, line 8.

In response thereto, Applicants have amended claim 224 to recite that introduction of positive or negative pressure to said contact member fixes a present shape of said contact surface. Support for this amendment can be found, for example, in claim 1, prior to the amendment of claim 1 in the response filed on May 2, 2011, and throughout the specification.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the objection to claim 224 as being no longer appropriate.

### **Claim Rejected Under 35 U.S.C. Section 102(e) (Boyd et al.)**

Claims 1, 224, 226-228 and 230 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Boyd et al., U.S. Patent No. 5,799,661.

The Examiner asserted, *inter alia*, that Boyd et al. discloses a device in Figs. 42-44 that includes a flexible main body 238 having a contact surface and an elongated malleable member extending along a length of said flexible main body member (metal wire) (column 21, lines 25-45).

The Examiner further asserted that the wire disclosed by Boyd et al. is capable of being shaped to engage the surface of the beating heart, is capable of being continuously adjustably shapeable by manipulation thereof to a desired shape and wherein upon release of manipulation forces, it maintains the desired shape and maintains a contact surface in the desired shape.

Applicants strongly traverse. It is respectfully submitted that Boyd et al. discloses at column 21, lines 37-40, that the wire that the Examiner has interpreted as a "malleable member" is rather, a "resilient metal wire, such as spring temper stainless steel or a superelastic nickel/titanium alloy, or a composite of metal and plastic. As such, this wire behaves opposite to the characteristics of the malleable member that is currently recited in claim 1. Specifically, contrary to the Examiner's

assertions, a resilient wire such as a spring steel or superelastic nickel-titanium alloy wire resiliently returns to its original configuration if forces are applied to it to change its shape and then those forces are released. The properties “resilient” and “superelastic” are antagonistic to the properties of a material that is capable of being continuously adjustably shapeable by manipulation thereof to a desired shape and wherein upon release of manipulation forces, it maintains the desired shape and maintains a contact surface in the desired shape. This fact is further supported by Figs. 43 and 44 of Boyd et al. and the descriptions thereof. In Fig. 43, the resilient wire is manipulated so that it substantially straight. In Fig. 44, when the flexible heat exchanger 231 is inflated, the resilient wire returns to its curved configuration, and does not maintain the contact surface of the heat exchanger as flat or straight, as the surface is curved, as shown in Fig. 44.

Likewise, a superelastic material is a material that has an elastic (reversible) response to an applied stress. Therefore, it cannot be “continuously adjustably shapeable by manipulation thereof to a desired shape, and wherein upon release of manipulation forces, said malleable member maintains said desired shape and maintains said contact surface in said desired shape” as recited in claim 1.

Accordingly, it is respectfully submitted that the resilient or superelastic wire of Boyd et al. is not capable of being “continuously adjustably shapeable by manipulation thereof to a desired shape, and wherein upon release of manipulation forces, said malleable member maintains said desired shape and maintains said contact surface in said desired shape” contrary to the Examiner’s assertions.

The Examiner further asserted that the ... “malleable member maintains said desired shape and maintains a contact surface in the desired shape (column 19, lines 60-65 disclose that the wire is made of titanium allow (sic, alloy) (also see column 21, lines 30-40) and such a material is malleable and capable of performing the intended function)...”.

Applicants respectfully traverse. As already noted above, Figs. 43-44 and the descriptions thereof contradict the Examiner’s assertions. Specifically, the straight configuration of the wire in Fig. 43 is not maintained when the flexible heat exchanger is inflated, as shown in Fig. 44. Thus, the wire is not capable of being adjustable shapeable by manipulation thereof and then maintaining that shape after release of the shaping forces to as to maintain the shape and maintain a shape of a contact surface.

Further, the Examiner’s reference to column 19, lines 60-65 is misplaced, as this portion of the disclosure is directed to the retraction device of Fig. 36, not to the flexible heat exchanger of Figs. 42-44. Accordingly, the wire or band 214 is part of the retraction device 210, not a part of the flexible heat exchanger 231 as implied by the Examiner.

In view of the remarks, the Examiner is respectfully requested to reconsider and withdraw the

rejection of claims 1, 224, 226-228 and 230 under 35 U.S.C. Section 102(e) as being anticipated by Boyd et al., U.S. Patent No. 5,799,661, as being inappropriate.

**Claim Rejected Under 35 U.S.C. Section 103(a) (Boyd et al. in view of Buckman, Jr. et al.)**

Claims 225 and 229 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Boyd et al., U.S. Patent No. 5,799,661, in view of Buckman, Jr. et al., U.S. Patent No. 5,582,580.

The Examiner asserted that Boyd et al. disclose the invention substantially as claimed except for a device that includes a means for introducing positive/negative fluid pressure to the contact member.

Applicants respectfully traverse and submit that Boyd et al. fails to disclose, teach or suggest a contact member that is variably shapeable to a plurality of different shapes as claimed, or an elongated malleable member as claimed, or a having a shaft connected to said contact member as claimed.

The Examiner asserted that Buckman, Jr. et al. teaches a contact member 82 that is malleable (Fig. 7, column 9, line 28-column 10, line 63) and that it would have been obvious to modify the device of Boyd et al. to include a means for introducing pressure to the contact member, as taught by Buckman, Jr. et al. in order to provide an alternate means of shaping the contact member that allows the contact member to have a plurality of different shapes.

Applicants respectfully traverse. It is respectfully submitted that Buckman, Jr. et al. does not disclose a malleable contact member 82, but rather that 82 is a heart contacting member having a flexible sidewall, see column 9, lines 46-48. Further, Buckman, Jr. et al. applies pressure to the contact member to apply a massaging motion to the heart. There would have been no need for this functionality in the hypothermia device 230 of Boyd et al. It is respectfully submitted that it would not have been obvious to modify Boyd et al. as suggested by the Examiner, as this would only overcomplicate (and add to the expense of) the design of the heat exchanger, with little or no value or advantage to be gained therefrom.

Further, neither Boyd et al. nor Buckman, Jr. et al., whether taken alone or in any proper combination, discloses, teaches or suggests a malleable member that is continuously adjustably shapeable by manipulation thereof to a desired shape, and wherein upon release of manipulation force, said malleable member maintains said desired shape. It is respectfully submitted that this claimed characteristic is the opposite of what is disclosed by Boyd et al., as the heat exchanger and backbone of Boyd et al. resiliently return to an unfolded position after manipulation thereof and release of manipulation forces. Likewise, the walls 84 of member 82 of Buckman, Jr. et al. are not malleable as

claimed.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 225 and 229 under 35 U.S.C. Section 103(a) as being unpatentable over Boyd et al., U.S. Patent No. 5,799,661, in view of Buckman, Jr. et al., U.S. Patent No. 5,582,580, as being inappropriate.

### **New Claims 231-234**

New claims 231-234 have been submitted above. Support for these claims can be found in claims 224-230 and throughout the specification and drawings. Applicants respectfully request the allowance of claims 231-234 in the next Official Action.

### **Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-005CON6.

Respectfully submitted,  
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